

(iv) Require that observation zones be maintained in outdoor areas adjacent to the physical barrier at the perimeter of the entity and be large enough to permit observation of the activities of people at that barrier in the event of its penetration;

(v) Provide for a minimum of four barriers for the protection of the Variola major or Variola minor virus, one of which must be a perimeter fence;

(vi) Require a numbered picture badge identification subsystem to be used for all individuals who are authorized to access Variola major or Variola minor without escort;

(vii) Require the use, at all times, of properly trained and equipped security force personnel able to interdict threats identified in the site specific risk assessment;

(viii) Identify security force personnel designated to strengthen onsite response capabilities, and that will be onsite and available at all times to carry out their assigned response duties;

(ix) Provide for security patrols to periodically check external areas of the registered areas to include physical barriers and building entrances;

(x) Require that all on-duty security force personnel shall be capable of maintaining continuous communication with support and response assets by way of security operations center;

(xi) Require that Variola major and Variola minor material in long term storage be stored in tamper-evident systems;

(xii) Require that all spaces containing working or permanent Variola major or Variola minor stocks be locked and protected by an intrusion alarm system that will alarm upon the unauthorized entry of a person anywhere into the area;

(xiii) Require that alarms required pursuant to this section annunciate in a continuously manned security operations center located within the facility; and

(xiv) Require that the security operations center shall be located within a building so that the interior is not visible from the perimeter of the protected area.

(g) In developing a security plan, an individual or entity should consider the document entitled, "Security Guidance for Select Agent or Toxin Facilities." This document is available on the National Select Agent Registry at <http://www.selectagents.gov/>.

(h) The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident. Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and the names of registered entity personnel participants.

[70 FR 13316, Mar. 18, 2005, as amended at 77 FR 61112, Oct. 5, 2012; 79 FR 26862, May 12, 2014; 82 FR 6293, Jan. 19, 2017]

§ 73.12 Biosafety.

(a) An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested. The biosafety plan must include the following provisions:

(1) The hazardous characteristics of each agent or toxin listed on the entity's registration and the biosafety risk associated with laboratory procedures related to the select agent or toxin;

(2) Safeguards in place with associated work practices to protect entity personnel, the public, and the environment from exposure to the select agent or toxin including, but not limited to: Personal protective equipment and other safety equipment; containment equipment including, but not limited to, biological safety cabinets, animal caging systems, and centrifuge safety

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containers; and engineering controls and other facility safeguards;

(3) Written procedures for each validated method used for disinfection, decontamination or destruction, as appropriate, of all contaminated or presumptively contaminated materials including, but not limited to: Cultures and other materials related to the propagation of select agents or toxins, items related to the analysis of select agents and toxins, personal protective equipment, animal caging systems and bedding (if applicable), animal carcasses or extracted tissues and fluids (if applicable), laboratory surfaces and equipment, and effluent material; and

(4) Procedures for the handling of select agents and toxins in the same spaces with non-select agents and toxins to prevent unintentional contamination.

(b) The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).

(c) In developing a biosafety plan, an individual or entity should consider:

(1) The CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories." This document is available on the National Select Agent Registry Web site at <http://www.selectagents.gov>.

(2) The "NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules," (NIH Guidelines). This document is available on the National Select Agent Registry Web site at <http://www.selectagents.gov>.

(d) The biosafety plan must include an occupational health program for individuals with access to Tier 1 select agents and toxins, and those individuals must be enrolled in the occupational health program.

(e) The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident. Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems that were identified and

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corrective action(s) taken, and the names of registered entity personnel participants.

[70 FR 13316, Mar. 18, 2005, as amended at 77 FR 61114, Oct. 5, 2012; 82 FR 6293, Jan. 19, 2017]

§ 73.13 Restricted experiments.

(a) An individual or entity may not conduct, or possess products resulting from, the following experiments unless approved by and conducted in accordance with the conditions prescribed by the HHS Secretary:

(1) Experiments that involve the deliberate transfer of, or selection for, a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture.

(2) Experiments involving the deliberate formation of synthetic or recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD₅₀ <100 ng/kg body weight.

(b) The HHS Secretary may revoke approval to conduct any of the experiments in paragraph (a) of this section, or revoke or suspend a certificate of registration, if the individual or entity fails to comply with the requirements of this part.

(c) To apply for approval to conduct any of the experiments in paragraph (a) of this section, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued.

[70 FR 13316, Mar. 18, 2005, as amended at 77 FR 61114, Oct. 5, 2012; 79 FR 26862, May 12, 2014]

§ 73.14 Incident response.

(a) An individual or entity required to register under this part must develop and implement a written incident response plan based upon a site specific risk assessment.² The incident response plan must be coordinated with any entity-wide plans, kept in the

²Nothing in this section is meant to supersede or preempt incident response requirements imposed by other statutes or regulations.